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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/091,561	08/21/98	PLOUET J	USB95ARCNR

000466
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HM12/0925

EXAMINER	
EWOLDT,G	
ART UNIT	**PAPER NUMBER**
1644	24

DATE MAILED: 09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/091,561	Applicant(s) Plouet et al.
	Examiner G. R. Ewoldt	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *7/12/01 and 8/10/01* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *18-35* is/are pending in the application.

4a) Of the above, claim(s) *18-24 and 31* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *25-30 and 32-35* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. The request filed on 8/10/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/091,561 is acceptable and a CPA has been established. An action on the CPA follows.

2. A restriction was required under 35 U.S.C. § 121 in the parent application, as set forth in Paper No. 6, mailed 12/08/99.

Applicant elected Group IV, claims 25-30 and 32-35, drawn to anti-idiotype antibodies, with traverse. This restriction requirement is hereby reiterated.

The requirement is still deemed proper for the reasons of record as set forth in Paper No. 10, mailed 5/10/00, and is therefore made FINAL.

3. Claims 18-24 and 31 stand withdrawn from further consideration by the examiner as being drawn to non-elected invention.

Claims 25-30 and 32-35 are being acted upon.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25-30 and 32-35 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation, for the reasons of record set forth in Paper Nos. 10 and 18, mailed 5/10/00 and 3/12/01 respectively.

Applicant's arguments, filed 7/12/01, have been fully considered but have not been found persuasive. Applicant argues that "Claim 30 has been amended to teach a method of obtaining both monoclonal and polyclonal antibodies." However, Applicant is simply incorrect; performing the method of Claim 30 would not result in a monoclonal antibody being produced. The production of a monoclonal antibody requires several additional screening and isolation steps. Applicant further argues that the screening processes disclosed on page 17 woould enable any person skilled in the art to make and use the claimed invention. It is the Examiner's position that such is not the case. It is the Examiner's position that the methods disclosed in the specification would result in a polyclonal antiserum. Said polyclonal antiserum would comprise a mixture of antibodies that would bind both flt and flk-1. It is the Examiner's position that it would require undue experimentation to produce the antibodies of the instant claims, except as monoclonal antibodies. See for example the results on page 5 of Inventor Plouet's declaration, filed 9/11/00, which indicate that in one experiment, 3/4 of the antibodies produced were not specific for flk-1. A polyclonal antiserum (from which a polyclonal antibody would be isolated) would be expected to comprise a mixture of antibodies, some would bind flk-1, some would bind flt, and some would bind both. Such is the nature of a polyclonal antibody. Said polyclonal antibody then could not meet the limitations of the claims.

Applicant further argues that Fab fragments coupled to a toxin could prevent proliferation of endothelial cells. However, said conjugates would both fail to meet all the claimed limitations and further comprise additional unclaimed limitations.

6. The following are New Grounds of Rejection.

7. Claim 30 is rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically: "an immunoadsorption on an affinity column prepared with the pre-immune Ig of the animal which has been used to produce the anti-VEGF IgG".

Applicant's amendment, filed 7/12/01, asserts that no new matter has been added, however, the cited passage on page 8 does not disclose this broadening of the claim from rabbit to animal. Applicant's argument that "A mouse is an animal and, when it produces antibodies, it produces monoclonal antibodies," is both irrelevant and scientifically absurd. The specification as filed disclosed only "rabbit."

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
September 24, 2001

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600